

## REMARKS

Favorable reconsideration is respectfully requested.

The claims are 1 to 6.

Claims 1 to 5 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 4,464,376 to Sunshine in combination with Kreutner.

This rejection is respectfully traversed.

The present invention is directed to a pharmaceutical composition which contains efletirizine as an active principal and combines at least one fraction which allows immediate release of the efletirizine and at least one fraction which allows prolonged release of the efletirizine. The composition is particularly suitable for administration in a single daily dose. (See page 1, lines 16 and 17 of the specification).

Turning to the cited references, Kreutner describes a method of relieving symptoms of rhinitis comprising administration of an antihistaminically effective amount of one or more histamine H1 receptor antagonists and an amount of one or more histamine H3 receptor antagonists. Efletirizine is cited as being an histamine H1 receptor antagonist amount 40 other histamine H1 receptor antagonists. Moreover in the examples, the experimental data concern loratadine and descarboethoxyloratadine only; efletirizine is not exemplified.

There is nothing in Kreutner to motivate a person of ordinary skill in the art to choose efletirizine as required in the claims from among the long list of Kreutner. Moreover, the composition according to Kreutner comprises an amount of one or more histamine H3 receptor antagonists.

Sunshine describes a pharmaceutical composition which allows for extended and immediate release comprising caffeine and one or more analgesic agents or caffeine and an anti-inflammatory agent. Efletirizine is not mentioned in Sunshine. However, the rejection relies on column 16, lines 16 to 26, which discloses “when such long acting drugs are employed, it is often desirable to include an additional (emphasis) analgesia-enhancing amount of caffeine in the composition in sustained release form;...”.

In reply, efletirizine of Kreutner is not a so called “long acting” drug, contrary to loratadine, this property is due to the very specific pharmacokinetic characteristics of efletirizine (and in particular half life, plasmatic elimination, oral clearance, etc.).

Moreover, the composition according to Sunshine comprises caffeine.

A person skilled in the art would not apply this especially focused disclose of Sunshine to efletirizine.

Moreover, if a person skilled in the art wishes to select an anti-inflammatory agent, he would select loratadine which is exemplified in Kreutner and which is a long acting drug as defined by Sunshine.

Lastly, in combining the disclosures of Kreutner and Sunshine, the obtained composition would comprise at least one histamine H<sub>3</sub> receptor antagonist and caffeine.

Accordingly, the rejection of claims 1 to 5 as unpatentable over Sunshine in view of Kreutner is untenable and should be withdrawn.

Claim 6 stands rejected as unpatentable over Sunshine, Kreutner and Guy for reasons of record.

As pointed out in the response of February 2, 2006, Guy relates to a time release pharmaceutical preparation containing aspirin as the active therapeutic agent and efletirizine is not mentioned.

Thus, the statement on page 4 of the Final Rejection that with regard to claim 6, Applicant offers no arguments in addition to those mentioned with respect to the combination of Sunshine and Kreutner is incorrect.

In any event, it is not clear how or why one of ordinary skill in the art would be motivated to combine Guy’s teaching of time release aspirin compositions with Kreutner’s histamine H<sub>1</sub> and H<sub>3</sub> receptor antagonist compositions and Sunshine’s teaching of time release caffeine- anti-inflammatory or caffeine-analgesic compositions. The only motivation to combine these references comes from Applicants’ own disclosure.

Accordingly, the rejections on prior art are untenable.


No further issues remaining, allowance of this application is respectfully requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact undersigned at the telephone number below.

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Respectfully submitted,

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